

REMARKS

The Amendments to the Claims

Claims 1-3, 15, 26, 32, 48, 56-59, and 61 have been amended to correct typographical errors or matters of form. Claims 11 and 13 have been amended to recite the full name of CMNM, Collection Nationale de Culture de Microorganismes. Claim 12 has been amended to recite that the amino acid sequence set forth in SEQ ID NO: 5 or portion thereof comprises a phosphorylated threonine at amino acid position 559 of SEQ ID NO: 5. The amendments to claims 11-13 are supported by the specification at, e.g., page 13, line 27, through page 14, line 4; page 14, line 26, through page 15, line 14; and page 76, lines 9-12. No new matter has been added by way of the amendments.

The Restriction Requirement

The Examiner has required restriction among the following groups of claims:

- I. Claims 1-19, drawn to an anti-NIK antibody, hybridoma producing the antibody, a preparation comprising the antibody, and a pharmaceutical composition comprising the antibody.
- II. Claims 26-30, drawn to a method of regulating a biochemical activity of a NIK molecule, the method comprising contacting the NIK molecule with an anti-NIK antibody.
- III. Claims 31-36, drawn to a composition of matter comprising a substrate covalently attached to a peptide having the amino sequence set forth in SEQ ID NO: 5.
- IV. Claims 45 and 46, drawn to a method for preparing a monoclonal antibody comprising growing a cloned hybridoma.
- V. Claims 47-51, drawn to a method for identifying a ligand capable of inducing NIK-mediated NF κ B activation in a cell.

VI. Claims 52-59, drawn to a method of treatment of a disease caused or aggravated by the activity of NIK, comprising the administration of an anti-NIK antibody.

VII. Claims 60 and 61, drawn to a method for the purification of a NIK binding protein.

The Examiner also required an election of species requirement with respect to one of the diseases recited in claim 58 if Group VI is elected.

The Requirement for Restriction Should be Withdrawn.

Unity of invention in a U.S. national-stage application under 35 U.S.C. § 371 is governed by 37 C.F.R. § 1.475, and a lack of unity may result in a restriction requirement. 37 C.F.R. § 1.499. Rule 475 provides that, even where a group of inventions is claimed in an application, the unity of invention requirement is satisfied if there is a unifying technical relationship involving “one or more of the same or corresponding special technical features.” “Special technical features” are “technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.” *Id.* The Patent Office guidelines relating to double patenting rejections apply to national-phase applications submitted under 35 U.S.C. § 371. M.P.E.P. §§ 823 and 1893.03(d).

The Office asserted that the technical feature uniting Groups I-VII is an anti-NIK antibody, which was assertedly disclosed in U.S. Patent No. 5,854,003 (“the ‘003 patent”) prior to the instant application. On the contrary, the NIK peptide disclosed in the ‘003 patent comprises a different amino acid sequence from that of the instant application. In particular, the peptide of the ‘003 patent contains a substitution at position 25 compared to the NIK sequence of the instant application. (See, e.g., the ‘003 patent at col. 3, lines 10-14 (“The NIK polypeptides of the invention include incomplete translates of SEQ ID NO: 1 which translates and deletion mutants of SEQ ID NO: 2 have human NIK-specific amino acid sequence, binding specificity or function and comprise Ala25.”).) SEQ ID NO: 5 of the instant application does not comprise an alanine at position 25. To the extent that the ‘003 patent discloses fragments of the mutant NIK comprising the substitution at position 25 (see, e.g., column 2, lines 13-17; and column 3, lines 9-14), the disclosure does not destroy the special technical feature of the instant claims. In addition, the NIK peptide recognized by the

instant anti-NIK antibody comprises a phosphorylated threonine at position 559 of SEQ ID NO: 5. The '003 patent neither teaches nor suggests this feature. Thus, the general description of antibodies that bind NIK in the '003 patent refers to antibodies directed against a different peptide than the anti-NIK antibody of the instant application, and does not anticipate or render obvious the anti-NIK antibody unifying the pending claims. Accordingly, the claims of Groups I-VII share a special technical feature, and should be examined together.

In view of the above, the restriction requirement imposed for asserted lack of unity of invention should be withdrawn in its entirety, and each of claims 1-19, 26-36, and 45-61 presently pending in this application should be examined together.

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